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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,689	12/08/2003	Todd K. Whitehurst	AB-311U	5724

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EXAMINER	
BERTRAM, ERIC D	

ART UNIT	PAPER NUMBER
3766	

MAIL DATE	DELIVERY MODE
01/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/730,689	**Applicant(s)** WHITEHURST ET AL.	
	Examiner Eric D. Bertram	**Art Unit** 3766	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 15 January 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: _____.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Attached.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☒ Other: See inlcuded Notice of References Cited (PTO-892).

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 1/15/2007 have been fully considered but they are not persuasive. Initially, the applicant argues that the microstimulator of Schulman is not of a size and shape suitable for placement in the spinal column. However, Schulman specifically discloses the dimensions of the microstimulator, which 2 mm in diameter x 10 mm long. While it would be quite clear to one of ordinary skill in the art that these dimensions easily fit within the spinal column of a patient, the Examiner includes the Medtronic reference ("Neurostimulation Systems") in support of this statement. King discloses that the lead that is implanted in the spinal column of a patient is the Medtronic 3587A paddle lead (Col. 5, line 10). According to page 4 of the Medtronic reference, the 3587A model (AKA the Resume II®) has dimensions of 8 mm x 2 mm. Based on this supporting reference, the microstimulator of Schulman clearly is of a size and shape suitable for placement in the spinal column.

2. In response to applicant's argument that King does not expressly state that an implantable stimulator is placed in the spinal column, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In this case, King teaches placing a lead with a plurality of electrodes in the spinal column of a patient

(Col. 5, lines 2-30). Based on this teaching, one of ordinary skill in the art would have found it quite apparent to be able to implant any electrodes that were art-recognized equivalents into the spinal column of a patient. As stated above, the microstimulator of Schulman contains a plurality of electrodes contained in a structure that is extremely similar in size and shape to the lead utilized by King. Schulman further states that the microstimulator may be implanted to electrically stimulate "any part of the body, in the brain, a muscle, nerve, organ or other body area" (Col. 3, lines 66-68), of which the spinal column would be included. Therefore, it is apparent that the lead of King and the microstimulator of Schulman are art-recognized equivalents as defined by MPEP 2183. Therefore, it would be obvious to one of ordinary skill to replace the lead of King with the microstimulator of Schulman since they both are of a size and shape to be implanted in the spinal column, and both provide electrical stimulation to nerves in the body through electrodes. If this is the case, then by implanting the microstimulator of Schulman into the spinal column, as suggested by King, one would inherently be implanting a stimulator in the spinal column since the electrodes and the stimulator are contained *within the same structure.* Despite the fact that they have equivalent size and purpose, utilizing the microstimulator of Schulman also means that the signal generator 14 of King does not need to be implanted, which provides the added benefit of reducing the trauma inflicted on the patient, and reduces the chance of infection, as pointed out in the previous Office Actions and below. Therefore, the 35 USC 103(a) rejection of independent claim 1 and its dependent claims is still considered proper.

3. Regarding claims 12 and 25, the applicant argues that Dooley does not teach stimulating a dorsal root that would affect blood stimulation in the chest. The Examiner respectfully disagrees. While the abstract of Dooley does indeed teach stimulating the C-6 dorsal roots in order to treat small artery disease of the upper extremities, further down that same column discloses a more general stimulation of the dorsal roots. Dooley states that "the stimulation of the cut end of a dorsal root would result in *vasodilation of the area subserved by the root*" (emphasis added). It is clear then that if one stimulated the dorsal root that subserved the cardiac vasculature, one would influence the blood circulation of that area. Since King already teaches stimulating the spinal cord as a treatment for ischemic pain in the heart (angina), but was merely silent as to stimulating the spinal roots, it would be obvious to one of ordinary skill in the art to modify the method of King for affecting blood circulation by specifically stimulating the dorsal roots, as taught by Dooley. Therefore, the 35 USC 103(a) rejection of claims 12-20 and 25 is still considered proper.

4. Regarding claim 24, King further points out that the sensor 40 may be placed against a nerve to sense nerve activity to the muscles that correlates with limb usage, and may be indicative of ischemia or impending ischemia (Col. 6, lines 20-27). Furthermore, King discloses that the sensor 40 may be placed in "any other location described above," which includes the dorsal roots (Col. 7, lines 38-41). Therefore, the 35 USC 103(a) rejection of claim 24 is still considered proper.

5. Regarding claims 21-23, the applicant argues that none of the references teach choosing stimulation and control parameters to target specific cell populations or vary

activity in them. However, King discloses varying the parameters to accomplish such goals in Col. 10, lines 8-24. Therefore, the 35 USC 103(a) rejection of claims 21-23 is still considered proper.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric D. Bertram whose telephone number is 571-272-3446. The examiner can normally be reached on Monday-Thursday from 8:30-7.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 3766

EDB

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